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Regulating Homeopathic Drugs: Pragmatic Solutions for the Food and Drug Administration

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Neither the formulas of the past nor the technology of the present proved to have any effect, beyond, perhaps, a certain reassurance for user and receiver.

— Johannes de Ketham, *Fasciculus Medicinae*, 1495¹

Homeopathy is a theory and practice of medicine that purports to treat symptoms of diseases with drugs that produce symptoms or reactions in the body similar to a given disease in a healthy person.² The foundation of homeopathy is the notion that “like treats like” (*similia similibus curentur*). As such, the word “homeopathy” itself is derived from the Greek words *homoios*, which means similar, and *pathos*, which means either suffering or disease.³

Although homeopathic drugs in the United States have been used by a limited number of patients and prescribed on a similarly small scale by physicians, pharmacists, and manufacturers, there has been a recent dramatic growth in their use.⁴ According to the American Homeopathic Pharmaceutical Association, “[t]he 1995 retail sales of homeopathic medicines in the United States were estimated at \$201 million and growing

²Distinct from homeopathic medicine, “allopathic medicine” is defined as a “treatment whose action is directly opposed to or incompatible with the effects of the disease.” Jeremy Swayne, *Homeopathic Method: Implications for Clinical Practice and Medical Science* 207 (1998). Unlike homeopathy, most conventional treatments are considered to be allopathic.

³See Compliance Policy Guide § 400.400, *Conditions Under Which Homeopathic Drugs May be Marketed* (1995), reprinted in <<http://www.fda.gov>> [hereinafter *Compliance Policy Guide*]; Isadora Stehlin, *Homeopathy: Real Medicine or Empty Promises?*, *FDA Consumer Magazine*, December 1996, reprinted in <<http://www.fda.gov>>. See also *Conditions Under Which Homeopathic Drugs May be Marketed*; Availability of Compliance Policy Guide, 53 Fed. Reg. 21728 (1988) (notice).

⁴See PAOLO BELLAVITE & ANDREA SIGNORINI, *HOMEOPATHY: A FRONTIER IN MEDICAL SCIENCE* ix (1995).

at a rate of 20 percent a year, [and] the number of homeopathic practitioners in the United States has increased from fewer than 200 in the 1970s to approximately 3,000 in 1996.”⁵ Additionally, a recent study concluded that the use of alternative medicine in the United States has “increased substantially” from 1990 to 1997.⁶

Despite the growth of both the use of homeopathic drugs and the homeopathic drug industry, the Food and Drug Administration (FDA) has not altered its regulatory scheme for homeopathic drugs.⁷ As a result, homeopathic drugs are allowed on the market without any evidence that they are either safe or effective. The growing use of homeopathic drugs suggests that the FDA should reconsider its stance on homeopathic drugs so as to ensure consumer safety but yet preserve consumer choice.⁸

⁵Stehlin, *supra* note 3. Another source indicated that the homeopathic drug industry was at \$250 million in the 1990s and growing at a rate of 20 to 25 percent. See DANA ULLMAN, *THE CONSUMER’S GUIDE TO HOMEOPATHY* 34 (1995). Moreover, 75% of chain drugstores are selling some homeopathic drugs as of 1994. See *id.*

⁶David M. Eisenberg, Roger B. Davis, Susan L. Ettner, Scott Appel, Sonja Wilkey, Maria Van Rompay & Ronald C. Kessler, *Trends in Alternative Medicine Use in the United States, 1990-1997*, 280 JAMA 1569, 1572, 1574 (1998) (reporting that the percentage of people who used a homeopathic drug within a year increased from 0.7% in 1990 to 3.4% in 1997)[hereinafter *Trends in Alternative Medicine*].

⁷However, the National Institutes of Health (NIH) has taken action to study alternative medicine in the United States. The NIH established the Alternative Medicine Program Advisory Council so that it may advise NIH “regarding the evaluation of alternative medical treatment modalities, including acupuncture and Oriental medicine, homeopathic medicine, and physical manipulation therapies.” National Institutes of Health, Notice of Establishment, 58 Fed. Reg. 65727 (1993) (notice). Since its creation, Congress has changed its name to the National Center of Complementary and Alternative Medicine and increased its budget to \$50 million from its previous \$20 million. See Charles Marwick, *Alterations are Ahead at the OAM*, 280 JAMA 1553, 1553 (1998).

⁸The FDA confronts similar difficulties with respect to the growing using of herbal remedies. This piece focuses only on homeopathic drugs, which are distinct from herbal remedies. For discussions on possible approaches that the FDA could take with respect to herbal remedies, see Edgard R. Cataxinos, *Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform*, 1995 UTAH L. REV. 561 (1995) and Scott Martin, Note, *Unlabelled “Drugs” as U.S. Health Policy: The Case for Allowing Health Claims on Medicinal Herb Labels; Canada Provides a Model For Reform*, 9 ARIZ. J. INT’L & COMP. L. 545 (1992).

I. The History and Practice of Homeopathy⁹

A.

The Rise of Homeopathy and its General Practice

Although homeopathy's principles date back as far as several thousands of years,¹⁰ the present practice of homeopathy follows the teachings of Samuel Hahnemann, a German physician who practiced in the late 1700s and 1800s.¹¹ Homeopathy developed in response to the use of harmful bleeding techniques and other dangerous techniques practiced by conventional practitioners over two centuries ago.¹² In the early 1700s bloodletting was one of the most common treatments for many different diseases, with some physicians removing as much as four-fifths of a patient's blood.¹³ In addition to bleeding, physicians employed other equally ineffective and yet highly dangerous methods. Such methods included blistering a patient, which involved the application of very hot substances that were thought "to draw out infections," inducing vomiting, which involved the use of dangerous chemicals, and purging of ones bowels using toxic chemicals.¹⁴

In contrast to these drastic and highly dangerous practices, homeopathy strove to treat conditions with very mild medications that were highly diluted.¹⁵ In developing homeopathic drugs to replace these methods, Samuel Hahnemann developed a theory of treatment that was centered around three main principles: "the law of similars, the minimum dose, and the single remedy."¹⁶

⁹For a brief and accessible background and explanation of homeopathy, visit the webpage of Healthy Net at <<http://www.healthy.net>>.

¹⁰See Angela A. Mickelson, William H. Dailey, Soram Singh Khalsa & Mary L. Kedak, Managed Care Potpourri IV: Where Oh Where is Complementary/Alternative Case, 19 Whittier L. Rev. 119, 122 (1997) [hereinafter Managed Care].

¹¹See Homeopathy and 'Homeopathy,' Answers on FDA WebPage, at 1, September 15, 1988, cited in <<http://www.fda.gov>> [hereinafter Homeopathy and 'Homeopathy'].

¹²See id.

¹³See Stehlin, *supra* note 3.

¹⁴Id. One such drug used to cleanse the bowels involved large doses of mercury and calomel. See id. This same concoction also caused hair loss, loosened teeth, and induced several other negative symptoms associated with acute mercury poisoning. See id.

¹⁵See Homeopathy and 'Homeopathy', *supra* note 11, at 1.

¹⁶Stehlin, *supra* note 3.

Hahnemann first began using this homeopathic method after discovering that a large dose of quinine (used to treat malaria) induced in his healthy body the same symptoms of malaria itself.¹⁷ From this discovery, he began to test other drugs in smaller dosages to determine how they affected the symptoms of the body.¹⁸ Through testing on himself, his family, and his friends, Hahnemann made several “provings”—experiments that tested the efficacy of various dosages of various herbs, minerals, and other substances.¹⁹ These provings, which were conducted on humans and resulted in symptom profiles, were used to verify the efficacy of a particular homeopathic drug.

Because of the strong adverse effects that these substances had on patients during these provings, Hahnemann began experimenting with smaller and smaller doses.²⁰ He believed that the smaller the dose, the stronger the drug’s strength and effectiveness became.²¹ Hahnemann, applying the law of infinitesimals, would repeatedly dilute the active ingredient by factors of ten.²² Each of these dilutions were followed by vigorous shaking – this was believed to “release[] the healing energy of the remedy.”²³ Although Hahnemann was aware of the fact that repetitive dilutions of the active ingredient by factors of ten would most likely create dosages in which not even a single molecule of the active ingredient existed, he still believed that “a spirit-like essence could remain that could help stimulate the body.”²⁴ Homeopaths rely on the existence of the active ingredients in very minute quantities despite the fact that even using current technology, it is unlikely that a chemical analysis of a homeopathic drug would yield enough information to identify its active ingredient.²⁵ Even more telling, Avogadro’s number (6.023×10^{23}) sets an experimentally proven limit on the amount of dilution of an active ingredients that will result in a solution that contains any of the active ingredient.²⁶ If

¹⁷See *id.*

¹⁸See *id.*

¹⁹See *id.*

²⁰See *id.*

²¹See *id.*

²²See *id.*

²³Mahlon W. Wagner, *Is Homeopathy ‘New Science’ or ‘New Age’?*, 1 SCI. REV. ALTERNATIVE MED. 7, 7 (1997).

²⁴*Homeopathy and ‘Homeopathy’*, *supra* note 11, at 1-2; see Stehlin, *supra* note 3.

²⁵See Stehlin, *supra* note 3.

²⁶See Stephen Barrett, “Alternative” Medicine: More Hype than Hope, in *Alternative Medicine and Ethics* 20-21 (James M.

the dilution exceeds 24X, “[p]roponents [of homeopathy] acknowledge that there is virtually no chance that even one original molecule would remain.”²⁷

Presently, prescription homeopathic drugs are still produced by repeatedly diluting the active ingredient by a factor of ten, where ten is usually denoted by “X,” the Roman numeral for ten.²⁸ For example, a 9X preparation has been diluted by a factor of ten, separately nine times so that the final solution contains only one part per billion of the active ingredient.²⁹

Finally, homeopathic treatments are considered to be patient specific rather than merely disease specific. In other words, homeopathic physicians attempt to give each of their patients a single remedy that is designed to treat all of the patient’s symptoms rather than providing the patient with independent remedies for each symptom.³⁰ By treating the patient as a whole, the homeopathic physician believes that she is able to treat together both the mental and the physical symptoms that the patient is experiencing.³¹ This holistic treatment attempts to focus not merely on addressing the patient’s symptoms alone, but also on the patient as a whole including consideration of the patient’s genetic history, family history, and body type.³² Consequently, homeopathy results in a more individualized treatment.³³

Humber & Robert F. Almeder, eds., 1998).

²⁷*Id.* at 21.

²⁸*Homeopathy and ‘Homeopathy’, supra* note 11, at 1-2.

²⁹*Id.*

³⁰*See* Stehlin, *supra* note 3.

³¹*See id.*

³²*See id.*

³³*See id.*

B. The Fall of Homeopathy

Homeopathy gained support in America following the studies of Hahnemann, but at the turn of the twentieth century, homeopathy began to fall into disrepute. This was a result of three main factors. First, the publication of the Flexner Report of 1910 attacked the validity of several schools of alternative medicine including schools of homeopathy. “Compiled by Abraham Flexner... the report... examined the then-existing medical schools in the United States and gave low grades to most of the schools which did not practice or teach allopathic medicine.³⁴ Many folded as a result.”³⁵ Consequently, most of the homeopathic schools fell into disrepute, leaving allopathic medicine as the dominant school of medicine.³⁶

Second, the increasing power of conventional medicine allowed it to act as an institution which ultimately turned against alternative forms of medicine with which it was in competition.³⁷ Efforts were taken to undermine the practice of homeopathy including “‘purg[ing]’ homeopaths from their ranks, including expulsion from medical societies, lawsuits, attacks in the medical literature, and attempts to turn public opinion against homeopathy.”³⁸

Finally, the rise of scientific medicine allowed conventional physicians to systematize their treatment and diagnosis of their patients.³⁹ This systemization of conventional medicine strengthened its power to unite against alternative forms of medicine. The paradigm of conventional, or orthodox, medicine will be discussed below in Part IV.A.4.(a).

³⁴For a definition of “allopathic medicine,” see *supra* note 2.

³⁵*Managed Care*, *supra* note 10, at 122. See generally NAOMI ROGERS, AN ALTERNATIVE PATH (1998) (providing a detailed history of Hahnemann Medical College).

³⁶See *Managed Care*, *supra* note 10, at 122.

³⁷Michael A. Cohen, *A Fixed Star in Health Care Reform: The Emerging Paradigm of Holistic Healing*, 27 ARIZ. ST. L.J. 79, 126 (1995).

³⁸*Id.* at 124.

³⁹*Id.* at 125.

II. The Efficacy of Homeopathy

There is both empirical and clinical evidence that suggests that homeopathy is valid. From an empirical standpoint, the fact that homeopathy has survived through centuries of use and has spread widely across the globe strongly suggests that it is effective.⁴⁰ Furthermore, long-term use of homeopathic drugs over the centuries has subjected them to a filtering process that attempts to weed out those drugs that either are found to be unsafe or ineffective.⁴¹ From a clinical (or what is often thought as a more scientific) perspective, although many of the studies that have been conducted in order to show the efficacy of homeopathic drugs were conducted with poor, unscientific methodology, there are a significant number of valid studies that suggest that homeopathic drugs may be effective.⁴² For examples, two independent meta-analyses have concluded that homeopathic treatment is independent of any placebo effect.⁴³ Although these studies indicate that further research is necessary, they do show promise that homeopathy might actually be an effective remedy. One study commented similarly: “The results of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo. But there is insufficient evidence from these studies that any single type of homeopathic treatment is clearly effective in any one clinical condition.”⁴⁴

While there are some hopeful reports regarding the efficacy of homeopathy,⁴⁵ there is still a need for signifi-

⁴⁰See BELLAVITE & SIGNORINI, *supra* note 4, at 38.

⁴¹See *id.* at 38-39.

⁴²See *id.* at 42.

⁴³See Klaus Linde, Nicola Clausius, Gilbert Ramirez, Dieter Melchart, Florian Eitel, Larry V. Hedges & Wayne B. Jonas, *Are the Clinical Effects of Homeopathy Placebo Effects? A Meta-analysis of Placebo-controlled Trials*, 350 THE LANCET 834, 834 (1997); David Reilly, Morag A. Taylor, Neil G. M. Beattie, Jim H. Campbell, Charles McSharry, Tom C. Aitchison, Roger Carter & Robin D. Stevenson, *Is Evidence for Homeopathy Reproducible?*, 344 THE LANCET 1601, 1601 (1994).

⁴⁴Linde, *supra* note 43, at 839.

⁴⁵See generally BELLAVITE & SIGNORINI, *supra* note 4 (providing an overview of both experimental studies and theoretical foundations of homeopathy); FUNDAMENTAL RESEARCH IN ULTRA HIGH DILUTION AND HOMEOPATHY (Jurgen Schulte & P. Christian Endler, eds., 1998) (examining various high dilution studies as well as other support of homeopathy); SIGNALS AND IMAGES: SELECTED PAPERS (Madeleine Bastide, ed., 1997) (providing a collection of technical papers that examine the efficacy of high dilution treatments on various biological systems); ULTRA HIGH DILUTION: PHYSIOLOGY AND PHYSICS (P.C. Endler &

cantly more scientific evidence to support both its effectiveness and its safety. Even though there is empirical and some clinical evidence that individual homeopathic drugs may be safe and effective, these facts cannot adequately defend both the safety and effectiveness of homeopathic drugs in absence of studies that clinically prove their effectiveness in individual clinical conditions.

Furthermore, the present studies cannot demonstrate the effectiveness of high-dilution drugs, which is a key principle of homeopathy. The journal *Nature* published an article, commonly known as the “Benveniste paper,” which suggested that high-dilution drugs were in fact efficacious.⁴⁶ The study claimed that solutions of antibodies could be greatly diluted and yet still create a reaction in a certain type of white blood cell with antibodies of the immunoglobulin E (IgE) type on its surface.⁴⁷ This claim supports the homeopathic theory that despite the very high dilution of the active ingredients, the solution remains effective. However, additional studies led to evidence that Benveniste’s study was flawed.⁴⁸ The follow-up report found that Benveniste’s study was both biased and poorly conducted. A supplier of homeopathic drugs paid the salaries of two of the co-authors.⁴⁹ Furthermore, the experiment was described as being inexact and not fully investigated.⁵⁰ One group of commentators reflected on the ramifications of the Benveniste paper: “This incident shows why the hesitation of scientists to accept dramatically new ideas without adequate review represents reasonable caution rather than conservative intransigence.”⁵¹

J. Schulte, eds., 1994) (providing a collection of technical papers that examine the efficacy of high dilution treatments).

⁴⁶E. Davenas, F. Beauvais, J. Amara, M. Oberbaum, B. Robinzon. A. Miadonna, A. Tedeschi, B. Pomeranz, P. Fortner, P. Belon, J. Sainte-Laudy, B Poitevin & J. Benveniste, *Human Basophil Degranulation Triggered by Very Dilute Antiserum Against IgE*, 333 NATURE 816 (1988); see also Robert Pool, *Unbelievable Results Spark a Controversy*, 241 SCIENCE 407, 407 (1988) (describing the controversy surrounding the Benveniste paper).

⁴⁷See Pool, *supra* note 46, at 407.

⁴⁸John Maddox, James Randi & Walter W. Stewart, “High-dilution” Experiments a Delusion, 334 NATURE 287 (1988).

⁴⁹See *id.* at 287.

⁵⁰See *id.* at 289-90.

⁵¹Bert Black, Francisco J. Ayala & Carol Saffran-Brinks, *Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 779 (1994).

Additionally, even when homeopathic drugs appear to be efficacious in some cases, these results can generally be attributed to several other alternative causes. First, in the absence of more thorough studies, there is no way of knowing whether the homeopathic drug caused the recovery or if, in fact, a placebo effect caused the patient's recovery.⁵² "Many who don't believe in homeopathy's effectiveness say any successful treatments are due to the placebo effect, or, in other words, positive thinking."⁵³ This is not to say that there is always a placebo effect,⁵⁴ but there are specific cases in which it has been found. For example, a study that tested the efficacy of *Rhus toxicodendron*, extracts of poison oak, which homeopaths use to treat osteoarthritis, found that the "effects of *Rhus tox.* 6X and placebo did not differ significantly."⁵⁵

Second, there is no way of knowing whether or not the patient's symptoms were relieved due to natural changes in symptoms through the course of a disease or even whether remission was induced by the treatment or had natural causes.⁵⁶ Many conditions, given time, will often go away on their own. This critique is particularly applicable to the use of over-the-counter (OTC) homeopathic drugs because of their application to only self-limiting conditions.

Third, in absence of a strict regulation of homeopathic drugs, it cannot be known whether the homeopathic drugs alone caused the suppression of the symptoms or if, in fact, the homeopathic drug contained an effective dose of another active ingredient that actually cured the disease.⁵⁷

Fourth, because it is difficult to measure the actual dosage of the active ingredient in the drug, there is no

⁵²William Jarvis, M.D., *Consumer Forum*, CONSUMER MAGAZINE, April 1997, reprinted in <<http://www.fda.gov>>.

⁵³Stehlin, *supra* note 3. However, the placebo effect cannot be the entire reason that homeopathic drugs are found to be effective because they have been found effective in both infants and animals, for whom the placebo effect is inapplicable. Furthermore, many patients who are treated with homeopathic drugs for chronic illnesses experience a "so-called healing crisis or homeopathic aggravation" in which the symptoms are increased. See BELLAVITE & SIGNORINI, *supra* note 4, at 40. This effect is inconsistent with the placebo effect. See *id.*

⁵⁴See generally Linde, *supra* note 43; Reilly, *supra* note 43.

⁵⁵Michael Shipley, Hedley Berry, Gill Broster, Michael Jenkins, Anne Clover & Ivan Williams, *Controlled Trial of Homeopathic Treatment of Osteoarthritis*, THE LANCET, January 15, 1983, at 97.

⁵⁶See Jarvis, *supra* note 52; Wagner, *supra* note 23, at 9.

⁵⁷See Jarvis, *supra* note 52.

way of telling if a dose of the drug actually contained an effective dosage of the active ingredient that could have actually caused the decline in the symptoms.⁵⁸

Fifth, patients who seek homeopathic treatment, have often found that traditional Western practices were ineffective, and hence see homeopathic drugs as remedies of a last resort. Under this mindset, users of homeopathic drugs might claim that the homeopathic medication is working despite the fact that they are still experiencing the symptoms of their ailment.⁵⁹

Sixth, representations that homeopathic drugs do in fact work effectively can be the source of fraudulent and inaccurate studies and reports.⁶⁰ For example, a clinical experiment purported that some homeopathic treatments might be useful in treating acute diarrhea in children; these results were published in the May 1994 issue of *Pediatrics*. However, in November 1995, another article appeared in *Pediatrics* that showed that the previous study was flawed in several respects.⁶¹ Although there was probably not fraudulent intent here, this example goes to support the fact that many studies that seemingly support the effectiveness of homeopathic drugs are flawed. “Although *Pediatrics* is published by the American Academy of Pediatrics, Jacobs’ study and several others published in such journals as *The Lancet* and the *British Medical Journal* are considered ‘scanty at best’ by the academy.”⁶²

Ultimately, although there is some scientific evidence that supports the effectiveness of homeopathy, there are several other factors and studies that suggest that homeopathy is ineffective. As a result, in order to determine whether homeopathy is in fact effective, much additional experimentation, using more rigorous methodologies is necessary.

⁵⁸ See *id.*

⁵⁹ See *id.*

⁶⁰ See *id.*

⁶¹ See Stehlin, *supra* note 3.

⁶² *Id.*

III. Homeopathy and its Treatment in Food and Drug Law

A. The History of Homeopathy in Food and Drug Law

Despite the fact that homeopathy had fallen into disrepute at the turn of the twentieth century as allopathic medicine became the dominant medical practice in the United States, homeopathy was still given an important status in the Federal Food, Drug, and Cosmetic Act of 1938 (1938 Act). As both the chief sponsor of the Federal Food, Drug, and Cosmetic Act of 1938 and also as a homeopathic physician, Senator Royal Copeland of New York amended the Food and Drugs Act of 1906 by defining “drug” to include those homeopathic drugs that are listed in the Homeopathic Pharmacopoeia of the United States (HPUS).⁶³ The HPUS is a “compilation of standards for source, composition, and preparation of homeopathic drugs,”⁶⁴ which the 1938 Act also recognized as an official compendium.⁶⁵ The 1962 amendments to the 1938 Act left this inclusion of homeopathic drugs within the statutory definition of “drug.”⁶⁶

⁶³See Compliance Policy Guide, *supra* note 3; *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2; Stehlin, *supra* note 3. Specifically, the Federal Food, Drug, and Cosmetic Act of 1938 defines “drug” as:

(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in (A), (B), or (C) of this paragraph.... A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1) (1998). See also *United States v. Writers & Research, Inc.*, 113 F.3d 8, 11 (2nd Cir. 1997) (finding that a homeopathic drug was subject to the requirements of the Act); *Meserey v. United States*, 447 F. Supp. 548, 552-53 (D. Nev. 1977) (confirming that homeopathic remedies, if listed in the HPUS, should be treated as drugs under the Act). It should be noted, however, that the FDA ultimately determines how homeopathic drugs will be regulated under the Act.

⁶⁴Compliance Policy Guide, *supra* note 3; see *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2; Stehlin, *supra* note 3.

⁶⁵See 21 U.S.C. § 321(j). “The term ‘official compendium’ means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.” *Id.*

⁶⁶See *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2.

B. The FDA's Current Stance on Homeopathic Drugs

The FDA treats homeopathic drugs, both prescription and OTC, quite differently than conventional or allopathic drugs. Perhaps most importantly, unlike conventional drugs, homeopathic drugs are not required to submit to pre-market approval, which involves filing for a new drug application (NDA) in order to market the drug. In fact, no homeopathic drug has successfully applied for an NDA. Because of this key exclusion, homeopathic drugs are marketed without having been proven to be safe or effective. Furthermore, unlike other OTC drugs, which are either required to submit to OTC Review or to apply for an NDA,⁶⁷ OTC homeopathic drugs are not required by the FDA to be tested for safety or effectiveness.⁶⁸ Arguably, the 1938 Act does require that homeopathic drugs meet the standards set forth by the Homeopathic Pharmacopoeia of the United States. However, this does not ensure their safety and effectiveness under the FDA's standards: a "product's compliance with requirements of the HPUS... does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use."⁶⁹

Other, perhaps less significant, differences between the way in which conventional and homeopathic drugs are regulated also exist. First, homeopathic drugs that are ingested in solid, oral dosages are required to be imprinted so that the imprint both identifies the manufacturer of the drug and indicates that the drug is homeopathic.⁷⁰ This requirement is less stringent than that which is required of other conventional drugs,

⁶⁷See *infra* Part IV.A.

⁶⁸Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464, 9466 (1972) (to be codified at 21 C.F.R. pt. 130).

⁶⁹Compliance Policy Guide, *supra* note 3. The Act also specifies the treatment of combined homeopathic and non-homeopathic drugs. The statute states:

Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

⁷¹U.S.C. § 351 (1998).

⁷⁰See Imprinting of Solid Oral Dosage For Drug Products for Human Use, 58 Fed. Reg. 47,948, 47,949, 47,951 (1993) (to be

which are also required to imprint on solid, oral dosages the active ingredient and strength of the dosage, rather than simply the manufacturer.⁷¹ Homeopathic drugs were exempted from this requirement because the FDA concluded that the costs of this requirement would outweigh any incremental safety benefits that would result, especially given the fact that homeopathic drugs are held to the standards of the HPUS.⁷² Second, homeopathic drugs in liquid form are held to a lower standard than are conventional drugs with respect to regulations on alcohol content.⁷³ Conventional OTC drugs intended for adult consumption are not allowed to be composed of more than ten percent of alcohol.⁷⁴ However, the FDA has exempted homeopathic drugs from this restriction.⁷⁵ The FDA succumbed to comments which suggested that the removal of alcohol as a common solution for the homeopathic treatments would undermine the integrity of homeopathic drugs and require completely new analysis of the efficacy of the drugs, a very costly requirement.

Despite the fact that homeopathic drugs are treated in a substantially different manner than conventional drugs, the FDA has placed several restrictions on the marketing of homeopathic drugs. The essence of the FDA's stance on the marketing of homeopathic drugs can be found its Compliance Policy Guide (CPG), "Conditions Under Which Homeopathic Drugs May be Marketed."⁷⁶

The scope of the FDA's definition of homeopathy is expressed in this CPG: the FDA defines homeopathy as "[t]he practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects," it defines a homeopathic drug as "[a]ny

codified at 21 C.F.R. pts. 206, 207, 314, 330); Stehlin, *supra* note 3.

⁷¹ See Imprinting of Solid Oral Dosage For Drug Products for Human Use, 58 Fed. Reg. at 47,949; Stehlin, *supra* note 3.

⁷² See Imprinting of Solid Oral Dosage For Drug Products for Human Use, 58 Fed. Reg. at 47,957, 47,950.

⁷³ See Stehlin, *supra* note 3.

⁷⁴ See Over-the-Counter Drug Products Intended for Oral Ingestion that Contain Alcohol, 60 Fed. Reg. 13,590, 13,590 (1995) (to be codified at 21 C.F.R. pt. 328); Stehlin, *supra* note 3.

⁷⁵ See Over-the-Counter Drug Products Intended for Oral Ingestion that Contain Alcohol, 60 Fed. Reg. at 13,593; Stehlin, *supra* note 3.

⁷⁶ Compliance Policy Guide, *supra* note 3.

drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopoeia of the United States (HPUS), an addendum to it, or its supplements.”⁷⁷ Thus, any homeopathic drug is required to be labeled as such. Furthermore, those drugs that contain homeopathic and non-homeopathic ingredients are considered to be non-homeopathic drugs.⁷⁸

Although the CPG on homeopathic drugs does not require any sort of pre-market approval, it does purport to subject homeopathic drugs to current good manufacturing practices, hold homeopathic drugs to several labeling requirements, monitor OTC versus prescription use of homeopathic drugs, and protect against fraud. First, the FDA does not allow health fraud with respect to homeopathic drugs. The CPG defines “health fraud” as:

The deceptive promotion, advertisement, distribution or sale of articles, intended for human or animal use, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes. Such practices may be deliberate, or done without adequate knowledge or understanding of the article.⁷⁹

Although this suggests that homeopathic drugs should be safe and effective, in fact, because they are not held to the requirement of pre-market approval, there is little way for the FDA to know if claims of many homeopathic drugs are in fact inaccurate because the drug is ineffective or unsafe.

Second, the FDA limits the marketing of nonprescription homeopathic drugs to those that treat only “self-limiting” conditions that the average consumer can recognize and diagnose.⁸⁰ As a result, homeopathic drugs that claim to reduce serious diseases that require actual diagnoses by a licensed physician, including AIDS and cancer, are required to be marketed as prescription only drugs.⁸¹ Otherwise, the distinction between prescription versus OTC status is determined according to section 353(b), as with conventional drugs.⁸²

⁷⁷ *Id.*

⁷⁸ *See id.*

⁸⁰ *See id.*; *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2-3; Stehlin, *supra* note 3.

⁸¹ *See* Compliance Policy Guide, *supra* note 3; *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2-3; Stehlin, *supra* note 3.

⁸² *See* Compliance Policy Guide, *supra* note 3.;

Under section 353(b), habit forming drugs and a drug, which “because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug,” are considered prescription drugs.⁸³

Third, the FDA requires that homeopathic drugs be properly labeled. Homeopathic drugs are required to comply with the labeling provisions of 21 U.S.C. § 352.⁸⁴ As part of this requirement, a “drug or device shall be deemed to be misbranded... [i]f its labeling is false or misleading in any particular.”⁸⁵ Furthermore, section 352 of the Act requires that the name and place of business of the manufacturer, packer, or distributor be placed on the package.⁸⁶ Homeopathic drugs for retail sale must also bear adequate directions for use that can be interpreted by the average lay person as required under section 352(f), their ingredients as well as their dilutions (which expresses how many parts per power of ten of the active ingredients that the drug actually contains), at least one major indication for the drug, the drug’s established name in accordance with section 352(e), and any applicable warnings.⁸⁷ Additionally, “[d]ocumentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.”⁸⁸

Prescription drugs should comply with the General Labeling Provisions required for nonprescription drugs

⁸³21 U.S.C. § 353(b)(1) (1998).

⁸⁴See Compliance Policy Guide, *supra* note 3.

⁸⁵21 U.S.C. § 352(a) (1998).

⁸⁶See *id.*; 21 U.S.C. § 352(b) (1998).

⁸⁷See Compliance Policy Guide, *supra* note 3. Section 352(f) indicates in pertinent part:

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 U.S.C. § 352(f) (1998). An exemption from adequate directions for use, as described in § 353(b)(2) is only allowed for prescription drugs. See Compliance Policy Guide, *supra* note 3.

⁸⁸Compliance Policy Guide, *supra* note 3.

as well as some additional requirements. As required by section 353(b)(4), all “[p]rescription homeopathic drugs must be labeled, ‘Caution: Federal law prohibits dispensing without prescription.’”⁸⁹ Prescription homeopathic drugs shall also include a statement of identity, declaration of net quantity of contents and statement of dosage, and a physician package insert.⁹⁰

Fourth, the FDA requires that homeopathic drugs generally be manufactured in conformance with current good manufacturing practice.⁹¹ However, there are two exemptions to this requirement.⁹² First, homeopathic drugs need not have expiration dating.⁹³ Second, the FDA proposed an amendment that exempted homeopathic drug products from the requirement for laboratory determination of identity and strength of each active ingredient prior to the release and distribution of the drug on the market.⁹⁴ Until there is a final ruling on this proposed amendment, the FDA has a policy not to enforce this regulation against homeopathic drugs.⁹⁵

C. Why Does the FDA Treat Homeopathic Drugs Differently?

There are several often-cited reasons for applying less strict regulations to homeopathic drugs than are applied to allopathic or conventional drugs. First, because homeopathic drugs, by design, contain such

⁸⁹ *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2-3; see Compliance Policy Guide, *supra* note 3.

⁹⁰ See Compliance Policy Guide, *supra* note 3.

⁹¹ See *id.*

⁹² See *id.*

⁹³ See *id.*; 21 C.F.R. § 211.165 (1998).

⁹⁴ See Compliance Policy Guide, *supra* note 3; Current Good Manufacturing Practice in Manufacture Processing, Packing, or Holding; Proposed Exemption from Active Ingredient Identity and Strength Testing for Homeopathic Drug Products, 48 Fed. Reg. 14,003 (1983) (to be codified at 21 C.F.R. pt. 211) (proposed April 1, 1983). The FDA argued that the minute benefits of requiring this testing of homeopathic drugs were outweighed significantly by the costs to the manufacturers of homeopathic drugs. See *id.* at 14,004. Also, the FDA felt that the restrictions of the Homeopathic Pharmacopoeia of the United States would sufficiently solve any risks that were caused by the exemption. See *id.*

⁹⁵ See *id.*

infinitesimal amounts of any given active ingredient, it is difficult to imagine that even active ingredients that could be toxic in certain dosages can ever have a toxic effect in a mixture in which it is only one part per million or even less.⁹⁶ As such, from a toxicity, poison-control standpoint, safety regulations that are applicable to conventional drugs should not necessarily be applied to homeopathic drugs.⁹⁷

Second, the FDA has considered homeopathic drugs to be distinct from conventional drugs and has hence traditionally separated its treatment of them as far as regulating them. New exemptions that the FDA has granted to homeopathic drugs are simply consistent with the FDA's longstanding approach of segregating regulation of homeopathic drugs from conventional medications.⁹⁸

Third, one must remember that the FDA does in fact have limited time and resources. The relative costs and benefits of regulating homeopathic drugs rather than expending energy in other areas of regulation must always be evaluated when considering new methods of regulating homeopathic drugs.

IV. Possible Alternative Approaches to the FDA's Treatment of Homeopathic Drugs

Despite the foregoing reasons that are often used to justify the continuation of the FDA's stance of inaction toward homeopathic drugs, the growing popularity and use of homeopathy suggests that the FDA should reconsider its policy of inaction toward homeopathic drugs. The FDA has a spectrum of alternative approaches to the regulation of homeopathic drugs.

⁹⁶See Stehlin, *supra* note 3. This reasoning was espoused by Edward Miracco, a consumer safety officer at the FDA's Center for Drug Evaluation and Research.

⁹⁷See *id.* (quoting Edward Miracco, a consumer safety officer at the FDA's Center for Drug Evaluation and Research). *But see infra* Part IV.A.3.(a).

⁹⁸See Stehlin, *supra* note 3.

A.

A commonly mentioned alternate treatment of homeopathic drugs is to require that they go through the same approval process as do conventional drugs.⁹⁹ Under this requirement, homeopathic drugs would have to be tested for both safety and effectiveness. This would require all homeopathic drugs¹⁰⁰ either to file an NDA or to submit to the OTC Review Process. As will be elaborated below, despite its advantages in terms of proving safety and effectiveness, this alternative will have devastating results on the homeopathic drug industry.

1. The Pre-market Approval Process

Conventional drugs are required to go through a rigorous, costly, and time-consuming testing process. To understand the consequences of such an approach it is important to address the process that pre-market approval of conventional drugs presently entails.

Currently, the FDA places conventional drugs in three different categories: (1) new drugs, (2) drugs that are generally recognized as safe (GRAS) and generally recognized as effective (GRAE), (3) and drugs that fall under the grandfather clauses of the 1938 Act or the 1962 amendments.¹⁰¹

Under section 321(p)(1) of the Act, in order for a drug to be considered GRAS and GRAE, the manufacturer must show that the drug is “generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions

⁹⁹This approach was advocated by Jarvis, *supra* note 52, and the National Council Against Health Fraud, *NCAHF Position Paper on Homeopathy*, Feb. 1994, in <<http://www.ncahf.org/pos-pap/homeop.html>>.

¹⁰⁰The FDA would still be unable to require pre-market approval of those homeopathic drugs that fall under the umbrella of the grandfather clauses of the 1938 Act or the 1962 amendments to the Act. *See infra* IV.A.1.

¹⁰¹*See* 21 U.S.C. § 321(p)(1) (1998).

prescribed, recommended, or suggested in the labeling thereof.”¹⁰² Although one might argue that homeopathic drug manufacturers could claim that their drugs are GRAS and GRAE, this will not excuse such manufacturers from showing that their product is safe and effective. “FDA has taken the view that general recognition of safety and efficacy on the part of qualified experts must be based on scientific evidence, rather than personal experience or anecdotes,”¹⁰³ and this requirement has been upheld by the Supreme Court.¹⁰⁴ As a result, it is unlikely that many homeopathic drugs will be able to withstand this requirement without conducting new clinical trials and experiments because of the lack of scientific studies that prove the effectiveness of many homeopathic drugs and, in particular, because of the inability to prove that any efficacy that is found is not caused by the placebo effect or is consistent with no treatment intervention.

Unlike the GRAS and GRAE exception, it is possible that many homeopathic drugs might fall under the umbrella of the Act’s grandfather clauses. There are two independent grandfather clauses. First, section 201(p) of the 1938 Act indicated that the safety requirement of the Act would not apply to those drugs that were marketed under the 1906 Act and for which the labeled representations were the same. This grandfather clause remained unchanged after the 1962 Amendments. The statute indicates that a drug is exempt from showing safety and effectiveness if “at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.”¹⁰⁵ The 1962 Amendments also created transitional grandfather provisions in section 107(c) of the Amendments.¹⁰⁶ The relevant parts of these provisions indicate that in order to fall under the grandfather clause a drug (1) must have been in commercial distribution prior to the passage of the Act on October 9, 1962; (2) must have not been a new drug under the 1938 Act;

¹⁰²*Id.*

¹⁰³Joseph A. Page, *Federal Regulation of Tobacco Products and Products that Treat Tobacco Dependence: Are the Playing Fields Level?*, 53 FOOD & DRUG L.J. 11, 17 (1998).

¹⁰⁴*See* Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973), *cited in* Page, *supra* note 103, at 17.

¹⁰⁵21 U.S.C. § 321(p)(1) (1998).

¹⁰⁶These provisions are not codified in the statute.

(3) must not have been covered under a new drug application as of the passage of the Act on October 9, 1962; (4) and must have been intended solely for use under conditions prescribed, recommended, or suggested in the labeling with respect to such drug as of October 9, 1962.¹⁰⁷ Despite the breadth that these statutory exceptions might suggest, the courts have interpreted these grandfather clauses narrowly:

[W]e construe the critical language of the Grandfather Clauses to exempt drugs not generally recognized as effective if on the effective date of the Act the labeling contained the same representations concerning its use, and thus confine the exemptions to drugs intended solely for use under conditions prescribed on the effective date of the Act.¹⁰⁸

It is unclear, under this interpretation of the grandfather clauses, whether a significant number of homeopathic drugs would in fact fall under the umbrella of the grandfather clauses. Unlike conventional drugs of which few fall under the grandfather clause, it is possible that many more homeopathic drugs would fall under this umbrella. For example, the *Dictionary of Practical Materia Medica*, which describes several homeopathic drugs that are still used today, was available as early as 1900.¹⁰⁹ However, although it is true that many homeopathic drugs have been in use for centuries, it is unclear to what extent the labeling of these drugs and their indications of use have changed since 1962. In particular, it seems likely that the labeling of OTC homeopathic drugs might have changed more recently than prescription homeopathic drugs. Therefore, because most homeopathic drugs are sold OTC without a prescription,¹¹⁰ application of the grandfather clauses might be limited. It should, however, be noted that, under the current grandfather clauses, it is likely that many homeopathic drug manufacturers will claim to fall under the umbrella of the grandfather clauses.

New drugs are defined as those drugs that neither fall under the grandfather clauses nor are recognized

¹⁰⁷See Section 107(c)(4) of the 1962 amendments; Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 898 (1996).

¹⁰⁹JOHN HENRY CLARKE, M.D., A DICTIONARY OF PRACTICAL MATERIA MEDICA (1900).

¹¹⁰National Center for Homeopathy, *Homeopathy: Natural Medicine for the 21st Century* 4 (1993).

as GRAS and GRAE.¹¹¹ Because of the strict requirements for GRAS and GRAE, it seems reasonable to consider most homeopathic drugs that do not fall under one of the grandfather clauses as new drugs. The FDA requires that the FDA approve all new drugs before marketing them. This process of pre-market approval involves three stages: “(1) Preclinical research aimed at the discovery and identification of drug which is sufficiently promising to study in humans; (2) Clinical research to determine human efficacy and side effects (IND, Phases I, II, III)[; and] (3) FDA evaluation and approval of a new drug application (NDA).”¹¹² After the initial animal testing in Stage 1, drug manufacturers file a “Claimed Exemption for an Investigational New Drug” (IND), which the FDA has thirty days to review in order to determine whether human testing should occur. Stage 2 then involves three independent phases:

[In Phase I] ...the clinical pharmacologist has the responsibility of administering the drug to a human volunteer for the first time.... in order to ascertain drug metabolism and excretion and also to estimate the potential of the drug for producing adverse effects.... [Phase II is the] first time [the drug] is studied in patients with the disease which the drug is designed to treat.... The objective is to determine whether the drug has the desired therapeutic effect, the dose range at which this effect occurs, and whether any adverse effects observed will limit the drug’s usefulness.... [In Phase III] hundreds and even thousands of patients are investigated.... Usually masked, comparative studies with placebo or a standard drug are carried out, and great care is taken to detect adverse reactions and potential interaction of the new drug with other medications.¹¹³

After completion of Stage 2 and Stage 3 studies, the drug manufacturer files an NDA, which includes the results of the previous studies. The FDA then has at least 180 days to review the application.

During the FDA’s review process, the FDA makes the determination whether the new drug is both safe and effective. Specifically, section 355(d) of the Act requires the FDA to deny an application for a new drug if the application does not “include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed

¹¹¹See 21 U.S.C. § 321(p)(1) (1998).

¹¹²The Food and Drug Administration’s Process for Approving New Drugs, Report of the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Congress, 2nd Session (1980), *in* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 514 (2nd ed. 1991) [hereinafter Process for Approving New Drugs].

labeling thereof....” This determination was clarified in a Senate Committee meeting:

The decisionmaking process can conveniently be regarded as a three-step operation. . . .

Step 1. Determine the benefit to be derived from the drug;

Step 2. Determine the risk; and

Step 3. Weigh the benefit against the risk and decide whether it is in the public interest to approve the drug for marketing or to withdraw approval if the product is already on the market.¹¹⁴

Furthermore section 355(d) of the Act requires that the FDA deny a new drug application if it finds that “there is a lack of *substantial evidence* that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof....”¹¹⁵

The Act goes on to define “substantial evidence” as:

evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.¹¹⁶

The FDA Modernization Act of 1997 has clarified the standard of “substantial evidence” by allowing the FDA, at its discretion, to consider a single well-controlled study to be a sufficient showing of substantial evidence of efficacy.¹¹⁷

2. The OTC Review Process

Until the amendments to the Federal Food, Drug, and Cosmetic Act in 1962, very few OTC drugs had been approved by the FDA under the assumption that they were GRAS. However, the 1962 amendments required that all drugs be found to be effective as well. This created a formidable task for the FDA because

¹¹⁵21 U.S.C. § 355(d) (1998) (emphasis added).

¹¹⁷*Id.*

of the large number of OTC drugs (in the hundreds of thousands) that were already on the market. In response, FDA began what came to be known as the OTC Review. The OTC Review involved a massive effort to study the safety and effectiveness of the active ingredients of OTC drugs. As a key component of this Review, FDA established “panels of qualified experts to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise... on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded.”¹¹⁸ This determination relied upon human experience during marketing, expert opinion, published studies, and controlled clinical investigations.¹¹⁹ After the review process, the panel would categorize the drugs in either one of three categories:

Category I: OTC drugs that are generally recognized as safe and effective and not misbranded;

Category II: OTC drugs that were not generally recognized as safe and effective and misbranded; and

Category III: OTC drugs for which the data was insufficient.¹²⁰

Category I drugs were left on the market; category II drugs were removed from the market; and Category III drugs were left on the market until further studies were made available.¹²¹

¹¹⁸21 C.F.R. § 330.10(a)(1) (1999). The FDA defined safety as “a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall included results of significant human experience during marketing.” 21 C.F.R. § 331.10(a)(4)(i) (1999). “Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. Proof of effectiveness shall consist of controlled clinical investigations as defined in s. 314.126(b) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience marketing.” 21 C.F.R. § 331.10(a)(4)(ii) (1999).

¹¹⁹21 C.F.R. § 331.10(a)(4) (1999).

¹²¹*See id.*

3.

Advantages of Treating Homeopathic Drugs as Conventional Drugs

(a) Safety

Although the small amounts of active ingredients used in homeopathic drugs suggest that most homeopathic drugs are in fact safe, some can be dangerous. First, some homeopathic drugs have been found to contain substances that are harmful. For example, some homeopathic asthma treatments have been found to contain artificial steroids.¹²² Second, some homeopathic drugs are not substantially diluted and hence can have toxic effects. Four doses of homeopathic drugs containing mercury at a dilution of 4X will result in a toxic dose; a single dose of cadmium 6X is unsafe, and a 6X “dose of Aristolochia contains significant amounts of this cancer-causing herb.”¹²³ Although the toxic substances are supposed to be in high dilution, studies have found that some products have “notable quantities” of toxins; in one case two of six homeopathic drugs received by mail order contained notable quantities of arsenic.¹²⁴

Another safety concern associated with the use of homeopathic drugs is the lack of sufficient regulations over the practice of homeopathy. As mentioned above, there has been a dramatic increase of consumers seeking homeopathic treatments. With this demand, there has also been an increase in the supply of homeopathic drugs. As a result of this growing demand, there is a concern that not all homeopathic practitioners will be adequately trained to properly apply homeopathic treatments. The FDA should be concerned about these often unlicensed and untrained practitioners attempting to treat not only minor but also serious ailments

¹²² See National Council Against Health Fraud, *supra* note 99; Wagner, *supra* note 23, at 9.

¹²³ See Wagner, *supra* note 23, at 9.

¹²⁴ National Council Against Health Fraud, *supra* note 99.

such as AIDS and cancer with homeopathic treatments.¹²⁵ The problems associated with unlicensed and untrained practitioners only exacerbates the risks associated with homeopathic drugs because of the concern that even prescription homeopathic drugs will be misused and increase the risk that they are consumed in potentially toxic quantities.

By requiring that homeopathic drugs be tested for their safety in varying dosages, consumers can use and physicians can prescribe homeopathic drugs knowing that they are not at risk of harmful side-effects. Pre-market approval and the OTC Review should be able to adequately remove unsafe homeopathic drugs from the market.

(b) Efficacy

Currently, in the case of most homeopathic drugs, there is no evidence that they are in fact effective.¹²⁶ In absence of evidence that homeopathic drugs do in fact treat the ailments that they claim they can and do treat effectively, there is no proof that patients who seek homeopathic drugs are actually being treated. If in fact patients who use homeopathic drugs are not being adequately treated, these patients are delaying treatment that could be effective.¹²⁷ President Taft expressed this same view in an address to Congress in support requiring proof of efficacy of drugs: “There are none so credulous as sufferers from disease. The need is urgent for legislation which will prevent the raising of false hopes of speedy cures of serious ailments by misstatements of fact as to worthless mixtures on which the sick will rely while their diseases progress unchecked.”¹²⁸ Although use of homeopathic drugs to treat the common cold and other self-limiting diseases

¹²⁵ See *Homeopathy and ‘Homeopathy’*, *supra* note 11, at 2.

¹²⁶ See *supra* Part II.

¹²⁷ See Wagner, *supra* note 23, at 9.

¹²⁸ *Kar-ru Chemical Co. v. United States*, 264 F. 921 (9th Cir. 1920) (quoting 47 CONG. REC. pt. 3, 2379 (statement of President Taft)).

might not have large ramifications, some patients seek homeopathic treatment for serious life-threatening diseases such as AIDS and cancer. If the homeopathic drugs for these diseases are not effective, then these patients are delaying treatment that could, in effect, save their lives.

Pre-market approval of homeopathic drugs and the OTC Review would ensure that all homeopathic drugs on the market are effective. The drugs would be accompanied by studies that indicate the degree of their effectiveness. Both consumers and physicians will greatly benefit from the availability of this data when deciding whether to use homeopathic drugs.

(c) Non-homeopathic Drugs

Because drug manufacturers are not required to seek pre-market approval for homeopathic drugs, there is the risk that manufacturers will attempt to side-step the regulations of conventional drugs by marketing non-homeopathic drugs as homeopathic drugs.¹²⁹ For example, just recently CigArrest marketed their nicotine tablets and gum as homeopathic drugs. As homeopathic drugs, CigArrest was not required to seek pre-market approval for these new drugs, resulting in no testing for their safety and effectiveness. However, neither the active ingredients in nor method of intake of CigArrest products correlate to homeopathic practices; yet, they are marketed as homeopathic drugs. Because of this loophole, CigArrest has been marketing this conventional drug despite the fact that its active ingredient has been found ineffective previously. As argued in a petition by SmithKline Beecham, a manufacturer of a competing drug:

CigArrest is a prime example of a “homeopathic” product that undermines anti-smoking efforts. It does not appear to be a true “homeopathic” remedy; it is improperly labeled and promoted; it contains an active ingredient specifically prohibited several years ago by FDA from further marketing for smoking-cessation claims; it diverts smokers seeking help from proven effective remedies.¹³⁰

The FDA reviewed lobelia-containing smoking-cessation products, of which CigArrest is one, in its OTC

¹²⁹National Council Against Health Fraud, *supra* note 99.

review process and found that these were not effective.¹³¹ Despite this finding, CigArrest continues to market this product as a homeopathic drug that is not subject to OTC review.

By requiring that homeopathic drugs be subject to the same pre-market approval or OTC Review process as conventional drugs, this loophole for conventional drugs would be effectively closed. This would have two beneficial effects. First, by requiring pre-market approval for conventional and homeopathic drugs, the FDA can ensure that all conventional drugs are in fact proven to be both safe and effective. Even if homeopathic drugs are considered generally safe, the fact that conventional drugs can pass as homeopathic drugs raises the risk that unsafe or ineffective conventional drugs will be marketed as homeopathic drugs in an attempt to escape pre-market approval. Closing this loophole ensures the safety and effectiveness of all drugs.

Second, requiring that homeopathic and conventional drugs go through the same approval process will decrease the unfair competition between the two markets. With the current dichotomy between the treatment of homeopathic and conventional drugs, the market encourages manufacturers to market their drugs as homeopathic drugs in order to avoid the costs associated with, if not the preclusive effects of, the pre-market approval process. As a result, drugs that should not be considered homeopathic are being marketed as such.

(d) Insurance Coverage

Another often overlooked concern regarding the lack of proof of safety and effectiveness of homeopathic drugs is the possibility that with increasing use of alternative remedies, health insurers will cover these alternative remedies under their policies. For example, managed care is “increasing[ly] willing[] to cover complementary health care practices.”¹³² Although homeopathic treatments are not (or because they are

¹³¹See *id.* at 15.

¹³²Kathleen Boozang, *Western Medicine Opens the Door to Alternative Medicine*, 24 AM. J.L. & MED. 185, 187.

not) proven safe and effective, they are often cheaper than conventional treatments. As a result, there is an economic incentive for health insurers including Medicare and Medicaid to include alternative remedies and treatments under their coverage. This consequence has serious effects on the idea of consumer choice. It is reasonable to argue that, as long as a consumer consents to using alternative treatments she should not be restricted from doing so by the government. However, it would be unreasonable to require taxpayers, who might think that alternative remedies are at the same level as quackery, to compensate this person for her desire to use methods that are not proven to be safe and effective. If homeopathic drugs were to be covered under government insurance programs such as Medicare and Medicaid, then many taxpayers will be forced to expend money to support a theory of medicine that they are fundamentally opposed to because it has not withstood rigorous scientific testing.

Despite these concerns, presently, there are only low rates of insurance coverage for alternative treatments. Alternative treatments are rarely included in insurance benefits, and even when they are covered they are usually associated with high deductibles or subject to limitations.¹³³ However, an increase in insurance coverage will most likely be associated with the growing use and acceptance of alternative treatments.

4.

Disadvantages of Treating Homeopathic Drugs as Conventional Drugs

(a) Paradigm Shifting

Requiring homeopathic drugs to seek pre-market approval or submit to the OTC Review is counter to the very essence of homeopathy because it forces scientific regulations upon an industry that follows a different

¹³³See *Trends in Alternative Medicine*, *supra* note 6, at 1574.

paradigm or philosophy of thinking.¹³⁴ The existing regulations on medical practice in the United States strongly favor allopathic medicine over alternative forms of medicine. Michael H. Cohen explains:

[T]he existing regulatory environment favors a health care system dominated by orthodox medicine, based on technological approaches to disease and healing, and modeled on the assumption that patients lack the requisite sophistication to choose who may minister to the diseased body. This regulatory approach is not well suited to a health care system in which [alternative practitioners] and the patient share responsibility for the task of healing, in which patients value freedom of access to treatment, and in which patient autonomy supersedes paternalistic approaches to well-being.¹³⁵

Consequently, the current regulatory scheme results in a system in which allopathic practitioners are painted as “real” physicians whereas those that practice alternative medicine, including homeopathy, are seen as not practicing medicine at all or as practicing “quackery.”¹³⁶

The current paradigm focuses on the need to have scientific verification of medical procedures and medications. This focus is derived from the reliance of conventional medicine on “Cartesian dualism”: the notion that the mind is separate from the body. Hence, under the paradigm of conventional medicine, treatment of disease is seen as treatment of the body alone—not the patient as a combined unit of body and mind.¹³⁷ However, alternative medicine, including homeopathy, focuses not only on the body, but also on the patient as a whole—the mind and the body are treated as a single entity. This approach can be seen in homeopathy’s approach to providing a single dosage of a homeopathic drug to treat an individual rather than merely treating the individual symptoms of a patient separately.

Currently, however, a “paradigm shift” has begun to appear. A paradigm is defined as “a shared set of assumptions about the world, by which individuals define the parameters of their reality and their investigation of this reality.”¹³⁸ Because following the current paradigm results in acceptance “within the community, since

¹³⁴But see Linde, *supra* note 43, at 840 (“Deciding to conduct research on homeopathy recognises [sic] that this approach is a relevant social and medical phenomenon.”).

¹³⁶See Wayne B. Jonas, *Alternative Medicine—Learning from the Past, Examining the Present, Advancing the Future*, 280 JAMA 1616, 1616 (1998).

¹³⁷See Cohen, *supra* note 37, at 87.

¹³⁸*Id.* at 85.

they are committed to the consensus reality,” a shift in paradigms (or the emergence of a new paradigm) “generally occurs by revolution rather than by accretion.”¹³⁹ Paradigm shifts consist, generally, of consciousness of the new paradigm, alterations of the old paradigm, and resistance.¹⁴⁰ With the growth of both alternative medicine practitioners as well as consumer demand for alternative treatments, it seems as if we are amidst a paradigm shift (at least from the perspective of the patient): “It appears that complementary and alternative medicine has again ‘come of age’ in the United States.”¹⁴¹ Furthermore, many states, including Washington, already are defining homeopathy and some states are including homeopathy under their understanding of “health care professional.”¹⁴² Furthermore, Nevada and Arizona each have a distinct homeopathic licensing board.¹⁴³ These state efforts suggest that many states are shifting from the conventional notion of medicine to a view of medicine that includes alternative medicine. This paradigm shift is altering the concept of medicine from that of being purely scientific, orthodox medicine, to that of alternative medicine, which sees treatment in a more holistic fashion.¹⁴⁴

Recognition of the fact that homeopathy exists in an entirely different paradigm than conventional medicine raises the problem that subjecting homeopathic drugs to the same testing procedures as conventional medicine is an attempt to fit a regulatory scheme where it is inapplicable. Homeopathy relies on notions such as treating the patient as a whole, providing individualized treatments, and relying on the belief that the spirit of the active ingredient remains in the drug despite high-dilutions. These notions are inherently inconsistent with the conventional methods of scientific clinical studies because the very idea that homeopathic drugs are meant to have a consistent effect on different individuals is contrary to the practice

¹³⁹*Id.*

¹⁴⁰*Id.*

¹⁴¹Jonas, *supra* note 136, at 1616. At least one commentator believes that the paradigm shift is well on its way: “The popularity of [physicians in natural medicine has] signal[ed] the beginning of the end of orthodox medicine’s dominance of health care in the United States.” Boozang, *supra* note 132, at 187. Although this is probably an exaggerated viewpoint, it reveals at least the nature of the shift that is occurring, although at a slower rate.

¹⁴²Cohen, *supra* note 135, at 92, 95.

¹⁴³*See id.*

¹⁴⁴*See* Cohen, *supra* note 37, at 79.

of homeopathy.¹⁴⁵ It would be very difficult to create clinical trials for many homeopathic drugs because they are specific to the individual patient—any reproduction of the results would be very difficult if not impossible. From the perspective of homeopathy, the experience of the individual is more important than experimental results.¹⁴⁶ Furthermore, although homeopathy might appear to be consistent with allopathic medicine in some respects, homeopathy implicitly rejects allopathic medications, arguing that they merely mask a patient’s symptoms, leaving the disease untreated.¹⁴⁷

[A]lternative medicine comprises a large and heterogeneous group of treatments, many of which are procedures that are not readily testable under blinded conditions and for which the choice of appropriate control conditions is by no means straightforward. Furthermore, alternative medicine therapies may also possess a theoretical basis, may stem from a cultural tradition that is seemingly antithetical to a quantitative, biomedical framework, or may possess little foundational research on which to base a controlled evaluation.¹⁴⁸

Thus, the FDA must make a difficult and crucial choice regarding with which paradigm it wants to judge homeopathic drugs.

Adoption of the paradigm of conventional medicine has two major disadvantages: it entrenches the views of conventional medicine and it undermines consumer choice.¹⁴⁹ Although many might think that reliance on scientific evidence and conventional medicine are crucial aspects of health care, this very notion is entrenched in the paradigm of orthodox medicine. Use of this scientific paradigm serves to undermine both the availability and development of potentially effective alternative approaches to medicine.¹⁵⁰ Michael Cohen explains the negative effects that orthodox medicine has had on the development of alternative remedies:

¹⁴⁵ Cf. Practice and Policy Guidelines Panel, National Institutes of Health Office of Alternative Medicine, *Clinical Practice Guidelines in Complementary and Alternative Medicine*, 6 ARCHIVES OF FAMILY MED. 149,152 (“The individualization of treatment that characterizes [complementary and alternative medicine] is antithetical to the goals of practice guidelines, which tend to seek reductions in practice variation. This tension between individualization and uniformity represents another obstacle to practice guideline development....”).

¹⁴⁶ See Wagner, *supra* note 23, at 8 (noting the view of Dana Ullman, “a prominent spokesperson for American homeopathy”).

¹⁴⁷ See Cohen, *supra* note 135, at 111.

¹⁴⁹ See Cohen, *supra* note 37, at 80.

¹⁵⁰ See Cohen, *supra* note 135, at 86.

Many patients who might benefit from alternative healing modalities find themselves unable to afford, or even obtain, such treatments. Defenders of orthodoxy urge further randomized, double-blind studies proving efficacy. Yet, even as studies emerge, medical boards, insurers and lawmakers must move beyond a paradigm which, for historical and economic reasons, has dominated American health care since the late nineteenth century. The paradigm belittles or dismisses healing modalities outside medical orthodoxy, and reflects an overreliance on surgery and medication to heal disease.¹⁵¹

As another example of the clash between the two paradigms, medical boards, which have a great deal of authority over the licensing of physicians, have historically rebelled against physicians who practice homeopathic medicines.¹⁵² As long as the current orthodox paradigm remains dominant, it will continue to hold back alternative remedies. Subjecting homeopathic drugs to the same requirements as conventional drugs would probably remove most homeopathic drugs from the market because of their inability to meet the rigorous demands of science¹⁵³—not necessarily because homeopathic drugs are ineffective, but rather simply because homeopathic drugs are not suited to survive the testing scheme that has been established by orthodox medicine itself.¹⁵⁴

Second, the denial of entry of homeopathic drugs into the market undermines consumer choice and freedom. As long as the consumer is informed as to the present state of effectiveness and safety of any given drug, it seems unreasonable to allow the FDA to deny the consumer access to this drug simply because the FDA has determined that the drug is not safe and effective (as defined by orthodox medicine).¹⁵⁵ There is a strong demand for alternative treatments presently, and for the government to deny access to alternative

¹⁵²See *id.* at 111-14. Cohen refers to two independent cases, *In re Guess*, 393 S.E.2d 833 (N.C. 1990), *cert. denied*, 498 U.S. 1047 (1991), and *Metzler v. New York State Board for Professional Medical Conduct*, 610 N.Y.S.2d 334 (App. Div. 1994), *appeal dismissed*, 616 N.Y.S.2d 479 (N.Y. 1994), in which the courts upheld disciplinary actions against homeopathic physicians. See *id.* The medical board “appears to have singled out [the physicians] for termination of licensure merely because of [their] homeopathic leanings – just as allopathic physicians had singled out homeopaths for extinction some ninety years earlier.” *Id.* at 113; see *supra* Part I.

¹⁵³Even the less rigorous standards of the OTC Review would require scientific evidence that shows the efficacy of homeopathic drugs. This standard would be difficult to meet because of the large absence of clinical studies of homeopathic drugs.

¹⁵⁴But see FUNDAMENTAL RESEARCH IN ULTRA HIGH DILUTION AND HOMEOPATHY, *supra* note 45, at 6-7 (suggesting that homeopathic drugs can be submitted to conventional research strategies).

¹⁵⁵However, consumer choice only extends as far as adults and not children—children are not able to properly choose among treatments. See Stehlin, *supra* note 3.

treatments is governmental paternalism at its worst. Because consumers are increasingly seeking holistic approaches to medicine in which the physician sees the patient as a person and not merely as a disease to be treated, consideration of how to treat homeopathic drugs should not be made in a vacuum, independent of the consumer's interests.¹⁵⁶ Without proof that the consumer is actually at risk of harming herself, there seems to be little reason for the government to deny access to the consumer as long as her consent is informed. Unfortunately, the “softness’ of alternative medicine, which many regard as its main strength, is from the standpoint of conventional regulation, its chief weakness. It cannot stand up to standard modes of scientific inquiry—randomized clinical trials, double-blind studies, and the like—because, in important dimensions, it is more a philosophy than a protocol.”¹⁵⁷ Those who advocate that homeopathic drugs should show safety and effectiveness would argue that it is undeniable that consumers rely on the safety and effectiveness of homeopathic drugs; to this extent such drugs should be required to show that they can in fact survive this hurdle. To require otherwise would only serve to undermine not only consumer safety¹⁵⁸ but also consumer choice: without proof of safety and effectiveness, a consumer's choice to use homeopathic medicine is an entirely uninformed choice. Thus, the argument goes, the best means of preserving consumer choice is by providing consumers with choices that are actually proven to do what they claim to be able to do. “It is insufficient to say that, because randomized clinical trials are inappropriate for unconventional treatments, no testing at all need occur before a new therapy becomes the standard of care. If testing protocols are necessary, so be it.”¹⁵⁹

¹⁵⁶ See Mike Mitka, *FDA Never Promised an Herb Garden—But Sellers and Buyers Eager to See One Grow*, 280 JAMA 1554, 1554 (1998).

¹⁵⁷ Boozang, *supra* note 141, at 207-08.

¹⁵⁸ See *supra* Part IV.A.3(a).

¹⁵⁹ Boozang, *supra* note 141, at 208. See also Phil B. Fontanarosa & George D. Lundberg, *Alternative Medicine Meets Science*, 280 JAMA 1618, 1618 (1998) (“For virtually all medical therapies and interventions, whether conventional or alternative, determination of effectiveness and recommendations for clinical application should be based on the strength of the scientific evidence using explicit criteria for grading the quality of evidence and ratings for technology assessment....”).

Although states have the power to regulate the medical field (e.g., through overseeing the licensing of practitioners),¹⁶⁰ the FDA should be aware of this emerging paradigm shift and the effects that its policy could have on the current dichotomy between scientific medicine and alternative medicine when formulating changes in its approach to homeopathic drugs.

(b) Monetary Consequences

The most striking drawback of requiring homeopathic drugs to show safety and effectiveness is the large cost that it will have on the industry. The cost of the entire testing process as well as the NDA is placed entirely on the manufacturer. Furthermore, not only is the manufacturer required to pay for the tests, but the FDA also requires that the company pay user fees to reimburse the FDA for reviewing the NDA.¹⁶¹

The estimated cost to the manufacturer to test each drug for pre-market approval is high and growing.

The average cost of both researching and developing a new drug and filing a successful NDA is over \$230 million.¹⁶² Furthermore, the estimated time to go through the entire drug approval process has grown from

¹⁶⁰See Cohen, *supra* note 135, at 87. Of note, some of the deleterious effects of alternative medicine could be alleviated through a more stringent regulation of practicing homeopaths. For example, several states currently regulate the practice of homeopathic medicine through a licensing scheme. See *id.* at 92.

¹⁶¹New Drug and Antibiotic Application Review; Proposed User Charge, 50 Fed. Reg. 31,726 (1985) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1985).

¹⁶²See Walsh & Pyrich, *supra* note 107, at 931 (deriving this amount from a report from the Center for the Study of Drug Development at Tufts University). Another study presents an even higher estimate:

Pharmaceutical drug development costs have risen steadily over the last forty years. Data from various sources have estimated that the costs of discovering and developing a new drug have risen from about \$50,000,000 in the 1970s, through \$200,000,000 in the 1980s, and to \$400-\$500,000,000 today. The time required to develop a new drug also has increased, moving from about one year in the 1950s to over ten years today.

John F. Niblack, *Why are Drug Development Programs Growing in Size and Cost? A View From Industry*, 52 Food & Drug L.J. 151, 151 (1997) (“Marketplace factors of the 1990s are forcing developers of new drugs to increase development program content while they simultaneously strive to compress program length. Concurrently, regulatory and scientific requirements regarding the quality, quantity, and completeness of data are on the rise. This combination of factors is inflating new drug development costs markedly, and there are no signs of relief in sight.”).

two to three years in 1962 to as long as twelve years.¹⁶³ At these costs of both time and money to the manufacturer, the requirement that homeopathic drugs be subject to pre-market approval would almost certainly preclude their sale on the market. This is particularly the case because, although homeopathic drugs do in fact have a growing market, the market for them does not compare to that of allopathic drugs.

To put the costs in perspective, it is appropriate to consider the economic burdens of subjecting homeopathic drugs to the same restrictions as conventional drugs with respect to tests for merely identity and strength and restrictions on the use of alcohol in their drugs. The homeopathic industry made this same cost argument when the FDA proposed that homeopathic drugs be subject to the same restrictions as conventional drugs.¹⁶⁴ The homeopathic industry argued that these requirements would be far too costly because of the rigid testing requirements that they would require. In particular, with respect to the use of alcohol in liquid dosages, the comments suggested that this requirement would require an entirely new formulation of their drugs, which would require new tests for their efficacy. Even this limited amount of testing was argued to be formidable for the homeopathic drug industry.¹⁶⁵ It seems highly likely, as a result, that the requirement of proving safety and effectiveness of homeopathic drugs would, at least for most manufacturers and most drugs, preclude them from ever reaching the market.

Furthermore, the homeopathic drug industry is confronted with a unique problem of patenting issues. Unlike many conventional drugs, the majority of homeopathic drugs are derived from plants, making them unavailable for patenting.¹⁶⁶ “Most plant-derived drugs are categorized as ‘works of nature’ and, as such,

¹⁶³See Walsh & Pyrich, *supra* note 107, at 934. In 1980, the estimated time for the completion of pre-market approval testing was found to be between seven and thirteen years. See Process for Approving New Drugs, *supra* note 112, at 514.

¹⁶⁴See Over-the-Counter Drug Products Intended for Oral Ingestion that Contain Alcohol, 60 Fed. Reg. at 13,593.

¹⁶⁵Even the OTC Review would be costly for manufacturers of homeopathic drugs to the extent that they would have to perform clinical studies to show the effectiveness of their drugs. Even though there is a less stringent testing requirement, the homeopathic drug industry would be starting from scratch in terms of proof of effectiveness, making the costs to the industry high. It should also be noted that the OTC Drug Review has been an intense, difficult, and complicated regulatory scheme. See HUTT & MERRILL, *supra* note 112, at 609. It is still ongoing because of the sheer size of the project, and as a result, its priority within the FDA has fallen. See *id.* Thus, the costs to the FDA of extending the OTC Review to include homeopathic drugs should also be considered when evaluating the overall costs of this approach.

¹⁶⁶70% of homeopathic drugs are derived from plants. See Bob Leckridge, HOMEOPATHY IN PRIMARY CARE 15 (1997). The remaining 30% are prepared from other natural sources such as minerals and animals. See *id.*

are not patentable under current law.”¹⁶⁷ Under the current regulatory system, the effect of this is not felt because of the low cost of entering the market. However, requiring homeopathic drugs to submit proof of safety and effectiveness would create large costs to those manufacturers that choose to meet this burden. Furthermore, because these manufacturers could not patent their newly tested drug, there is little incentive for them to test them in the first place. With patentable drugs, “the U.S. market share for a drug declines immediately and precipitously upon expiration of its patent protection”;¹⁶⁸ it is reasonable to assume that absent a patent at all, homeopathic drug manufacturers would have no economic incentive to engage in the large costs of obtaining market approval.¹⁶⁹ The system would encourage manufacturers to hold out testing their own drugs until other manufacturers have incurred the costs of testing their own drugs. As a result of this holdout dilemma, there is the likely possibility that manufacturers will not seek approval of homeopathic drugs at all because of their lack of profitability.

(c)

As discussed above, requiring proof of safety and effectiveness of all homeopathic drugs would probably remove the availability of these alternative remedies from the market. The widespread decline in the availability of an increasingly popular alternative to orthodox medicine will probably carry with it large political ramifications for the FDA. As with the FDA’s once stringent regulations over dietary supplements,¹⁷⁰ the FDA will probably meet a great deal of political opposition with the adoption of such strict regulations of homeopathic drugs. The public largely sees the FDA’s role as regulating drugs for the benefit of the

¹⁶⁷Cataxinos, *supra* note 8, at 574 (citation omitted).

¹⁶⁸Niblack, *supra* note 162, at 153.

¹⁶⁹See Daniel P. Eskinazi, *Factors that Shape Alternative Medicine*, 280 JAMA 1621, 1622 (1998).

¹⁷⁰See *infra* Part IV.B.

public. However, by foreclosing an option that many people have sought out and are increasingly seeking out, the FDA could be perceived as over-stepping its regulatory function. In the absence of any evidence that homeopathic drugs are in fact unsafe, the FDA will could be seen as undermining consumer choice and freedom. The FDA was forced to capitulate with respect to dietary supplements, and will probably be forced to as well with respect to homeopathic drugs.

5. Conclusions on Treating Homeopathic Drugs as Conventional Drugs

Requiring proof of safety and effectiveness of homeopathic drugs would both have preclusive costs on the industry and unreasonably submit homeopathic drugs to tests that they are highly unlikely to survive. As a result, this piece suggests other alternatives that the FDA could utilize which would accomplish many of the same benefits of proving safety and effectiveness while not precluding homeopathic drugs from entering the market and thus undermining consumer choice.

B.

1. The Treatment of Dietary Supplements

One alternative would be to treat homeopathic drugs not as drugs at all, but rather define them to be dietary supplements. It should be noted, however, that this alternative would require a statutory amendment because, currently, a homeopathic remedy is defined as a “drug” in the Federal Food, Drug, and Cosmetic Act

of 1938—this was left unchanged in the 1962 amendments to the Act.¹⁷¹ However, assuming that such an amendment could be achieved, this alternative would allow homeopathic remedies to remain on the market without requiring them to go through a rigorous testing process.

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). This amendment to the Federal Food, Drug, and Cosmetic Act of 1938 was passed largely in response to political lobbying in favor of deregulating dietary supplements.¹⁷² “A national ‘Blackout Day’ was engineered by thousands of retailers of dietary supplements[, and a] lobbying day on Capital Hill was staged by the dietary supplement manufacturers.”¹⁷³

DSHEA classifies dietary supplements under a new and distinct category of food. Several changes from the 1938 Act’s approach to dietary supplements resulted. First, manufacturers of dietary supplements no longer have to prove that their products are safe prior to their marketing, as would be required had they been considered as food additives. Second, the amendment requires that FDA show that the dietary supplement has been adulterated under the 1938 Act—FDA bears the burden of proof.¹⁷⁴ Third, dietary supplements are permitted to make claims that the supplement positively affects the human body’s structure and/or function (structure/function claims) and certain authorized

“statements that pertain to a disease or health-related condition” (health claims), which previously could have caused dietary supplements to be regulated as drugs.¹⁷⁵ Specifically, DSHEA “allows dietary supplement labeling to bear a statement that ‘describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans’ or that ‘characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function. . . .’ Statements permitted under. . . the act

¹⁷¹See 21 U.S.C. § 321(g)(1) (1998).

¹⁷²See Peter A. Vignuolo, Note, *The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994*, 21 SETON HALL LEGIS. J. 200, 202-03 (1997).

¹⁷³*Id.* at 216-17.

¹⁷⁴See *id.* at 223-24.

¹⁷⁵Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. 23,624, 23,624 (1998) (to be codified at 21 C.F.R. pt. 101) (proposed April 29, 1998).

‘may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases,’ except that such statements may claim a benefit related to a classical nutrient deficient disease, provided that they also disclose the prevalence of the disease in the United States.”¹⁷⁶ “[A] dietary supplement manufacturer who wishes to make a permitted structure/function statement under...the act must have substantiation that the statement is truthful and not misleading, and must include in the state the following disclaimer: ‘This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.’”¹⁷⁷ The FDA also permits dietary supplements to make “certain statements that pertain to a disease or health-related condition [provided that the health claim is] authorized by FDA before they may be used on the label or in the labeling of a food or dietary supplement.”¹⁷⁸ Before the passage of DSHEA, both structure/function and health claims would classify the product as a drug under the Federal Food, Drug, and Cosmetic Act.

2. Advantages of Treating Homeopathic Remedies as Dietary Supplements

The main advantage of classifying homeopathic remedies in the same category as dietary supplements is that homeopathic remedies, which are not tested for safety and effectiveness, will no longer be marketed as drugs at all. Under this scheme, homeopathic remedies will not bear the imprimatur of conventional medicine. As a result, consumers choosing to take homeopathic remedies will be on notice that the remedy that they are consuming is not tested for safety and effectiveness and is not generally recognized by the

¹⁷⁶*Id.*; see 21 U.S.C. § 341(r)(6) (1998). If a dietary supplement is intended to be used to “diagnose, cure, mitigate, treat, or prevent a disease, then it can be treated as a drug. See *id.*

¹⁷⁷Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. at 23,624; see 21 U.S.C. § 341(r)(6) (1998).

¹⁷⁸Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. at 23,624; see 21 U.S.C. § 341(r)(1)(B) (1998).

conventional scientific community as safe and effective. Furthermore, by limiting the claims of homeopathic remedies to structure/function and approved health claims, rather than disease claims, the risk of consumer deception will be reduced.¹⁷⁹ Consequently, the harm that results from the delay of treating diseases caused by ineffective homeopathic remedies will likely be reduced as well. Although this approach does not ensure the safety and effectiveness of homeopathic remedies, it is no worse than the status quo with respect to the FDA's stance (or lack thereof) on showing the safety and effectiveness of homeopathic remedies.¹⁸⁰

Additionally, this approach would not subject homeopathic remedies to regulations that they are incapable by their very nature of surviving. By not subjecting homeopathic remedies to the standard of orthodox methodology, the alternative paradigm to conventional medicine will survive. Although it could be argued that, perhaps even more so than requiring pre-market approval of homeopathic remedies, the classification of homeopathic remedies as dietary supplements would clearly place homeopathic remedies outside of the field of medicine. As such, homeopathic remedies would be excluded from valid medicine, not on any meritorious ground, but solely because homeopathic remedies are seen as alternative remedies. As the argument goes, such a classification of homeopathic medicine would most likely further undermine its credibility without ever having the opportunity to prove its effectiveness. However, this argument is flawed because rather than requiring that homeopathic remedies be tested for safety and effectiveness, classifying them as dietary supplements would not require that they be held to the same standard (which is today purely an orthodox scientific one) as conventional drugs. As such, this approach would not force homeopathic remedies, which are not conducive by their very nature to the rigorous testing that is required of pre-market approval, to show their effectiveness through clinical trials. This would ultimately preserve the alternative medicine paradigm.

¹⁷⁹However, it should be noted that there is the inherent difficulty in distinguishing between disease claims and structure/function claims. As a result, it is unclear exactly how much of a beneficial effect limiting the claims of homeopathic remedies to structure/function claims will in fact have. *But see* Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. at 23,624 (attempting to clarify the distinction between disease claims and structure/function claims).

¹⁸⁰One could also require of homeopathic remedies the same labeling requirements that are currently specified in the Compliance Policy Guide even once they are classified as dietary supplements. This would provide almost the same benefits of the FDA's current stance on homeopathic remedies.

3. Disadvantages of Treating Homeopathic Remedies as Dietary Supplements

Despite the fact that treating homeopathic remedies as dietary supplements might appear to allow them to remain on the market, there are several impediments in the FDA's treatment of dietary supplements that will complicate this alternative.

First, it is unclear how homeopathic remedies would even be able to satisfy the requirements necessary to make structure/function claims. The FDA requires that all structure/function claims "must have substantiation that the statement is truthful and not misleading..."¹⁸¹ This requirement alone would be difficult for many homeopathic remedies to survive because it would require some degree of proof of efficacy of the remedy. The FDA's regulation of dietary supplement claims is far less rigorous than its regulation of drug claims. Of the approximate 2,300 structure/function notifications that the FDA has received since the passage of DSHEA, it has found only about 150 of them to be problematic.¹⁸² However, it seems that homeopathic remedy manufacturers would still confront difficulties in placing structure/function claims on their labels because they would be unable to substantiate their claims. Furthermore, it is even more unlikely that homeopathic remedies would be able to survive the FDA's requirements to make health claims. Under FDA's regulations, health claims must be accompanied by a summary that establishes that "based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."¹⁸³ Because homeopathic remedies would rarely be

¹⁸¹Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 63 Fed. Reg. at 23,624.

¹⁸²See Mitka, *supra* note 156, at 1555.

¹⁸³21 C.F.R. § 101.14, 101.70 (1999). Even if the FDA allowed dietary supplements to make general health claims based on authoritative statements, *see* 21 U.S.C. § 343(r)(2)(G) (1998), as recently proposed by the FDA, *see* Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements, 64 Fed. Reg. 3250 (1999) (to be codified at 21

able to produce this level of scientific certainty, they would probably be limited to making structure/function claims.

Second, it would be very difficult to limit the claims of homeopathic remedies to those of structure/function claims or health claims as opposed to claims to treat disease. Even if homeopathic remedies limited their labeling to claims regarding treatment of mere symptoms, many symptoms are clearly associated with diseases. As a result, few homeopathic remedies would be able to make the same claims that they do under the current regulatory system. Thus, although homeopathic remedies could still be marketed as dietary supplements, they would bear inadequate labeling for indications of use and directions for use because they would be unable to make claims as their effects on the body. This result would leave the consumer without any information regarding how and when to use homeopathic remedies, which would most likely lead to the misuse of these remedies.

Third, this reclassification is potentially dangerous because it would simply reduce the current regulations over homeopathic remedies. As dietary supplements, homeopathic remedies would not be subject to any regulations other than the labeling requirements associated with dietary supplements and the aforementioned restrictions. This solution would make no attempt to determine the safety and efficacy of such remedies, merely leaving potentially unsafe and ineffective remedies on the market (without adequate labeling). This problem is exacerbated by the existence of prescription-only homeopathic drugs. It is unclear how these could be treated as dietary supplements because they require the supervision of a physician to oversee their safe and proper use and application. The FDA would be forced to regulate these drugs independently in order to ensure that potentially unsafe products are not readily available on the market to the unwary consumer.

C.F.R. pt. 101) (proposed January 21, 1999), it is unlikely that many homeopathic manufacturers would be able to rely on this mechanism because of the lack of current research on homeopathic drugs.

4. Conclusions on Treating Homeopathic Remedies as Dietary Supplements

Although treating homeopathic remedies as dietary supplements would ensure that they would remain available to consumers to use if they so choose, it would result in the deregulation of the industry. This approach would ensure that homeopathic remedies are no longer treated as drugs and, as a result, misrepresented to consumers as safe and effective. However, because homeopathic remedies would be unable to substantiate their claims, they would be forced to market without indications for use, which would almost inevitably result in their misuse. Thus, this approach would only result in presenting less information and protection to consumers than the FDA's current regulations.

C. An Intermediate Solution—Creating a Regulatory System Specific to Homeopathic Drugs

Because of the difficulties associated with requiring homeopathic drugs to prove safety and effectiveness as well as the difficulties with decreasing the FDA's homeopathic drug regulations, an intermediate solution seems most appropriate. Because of the unique nature of homeopathic remedies, the FDA should design a regulatory structure that best meets the needs of patients and consumers while not undermining the stability of the entire homeopathic drug industry.¹⁸⁴

¹⁸⁴This intermediate design is similar to the approach that the European Community is attempting to design. Its stated goals are "to ensure the accessibility of homeopathic medicinal products, to guarantee the reliability and safety of these products, to guarantee information for users of homeopathic medicinal products, and to harmonize partially the rules regarding the production and monitoring of these products." Report on the Commission Report to the European Parliament and the

1. The Proposal

Rather than requiring homeopathic drugs to be proven both safe and effective under the standards of conventional medicine, the FDA could monitor homeopathic drugs and require that they be proven to be safe and effective, where effectiveness is viewed from the standpoint of homeopathy.¹⁸⁵ This scheme could be designed similarly to the process of OTC Review, in which the FDA creates monographs for particular active ingredients, except for three major differences.

First, it would include all homeopathic drugs, prescription and non-prescription, rather than being restricted to OTC drugs. Although most homeopathic drugs are sold OTC,¹⁸⁶ it is important to include prescription drugs under this review because prescription homeopathic drugs are most likely to contain doses of active ingredients that could be toxic.¹⁸⁷ Furthermore, it is important to ensure that as many homeopathic drugs as possible are included under review. For those homeopathic drugs that claim to fall under the grandfather clauses of the 1938 Act and the 1962 amendments, the FDA could take efforts to include as many as possible under this new scheme. Empirically, as the FDA successfully did with the OTC Review, the FDA could subject all OTC homeopathic drugs to this new requirement under the same rationale that the grandfather clauses do not apply to misbranding:

Council on the Application of Directives 92/73/EEC and 982/74/EEC on Homeopathic Medicinal Products, Committee on the Environment, Public Health and Consumer Protection, Oct. 28 1998, at 10. Of note, the EC is attempting to take a unique approach to homeopathic products in order to ensure the free marketing of homeopathic drugs. *See id.*

¹⁸⁵Because there is little difference between the allopathic and homeopathic understandings of safety it seems reasonable to subject homeopathic drugs to the conventional standard of safety.

¹⁸⁶*See* National Center for Homeopathy, *supra* note 110, at 4.

¹⁸⁷*See supra* Part III.B (noting that drugs with a high degree of toxicity are considered prescription drugs).

The [OTC] review... is designed to particularize not just the new drug provisions of the act, but also the misbranding provisions. Accordingly, the grandfather clauses in no way preclude the agency from reviewing, through a rule making procedure, the thousands of OTC drugs now on the market that are properly the subject of grandfather protection from the new drug provisions in order to make certain that they comply with the misbranding provisions of the act.¹⁸⁸

Furthermore, the FDA could attempt to include prescription drugs under this design as well, arguing that prescription drugs are also misbranded.

Second, a homeopathic drug review would require manufacturers to show that the drug is safe and effective, where effectiveness is defined from the perspective of homeopathy. The determination of “effectiveness” could be modeled after the approach taken by the Homeopathic Pharmacopoeia of the United States. This system both ensures that homeopathic drugs are safe and that they have adequate provings. Provings are similar to Phase 1 clinical trials of a new drug application:

Homeopathic drug provings on healthy volunteers are carried out according to Hahnemann’s classical directions, and also adhere to the current regulations for conventional clinical trials. Because homeopathic drug provings are pharmacological studies on healthy volunteers, they are quite similar to Phase I clinical trials as mentioned in current drug laws (good clinical practice).¹⁸⁹

These provings as well as tests on safety, could be used as the basis for monographs of the active ingredients of homeopathic drugs, which would ensure that homeopathic drugs are in fact safe and effective under the standards of homeopathy.

Third, the FDA would make efforts to have the expert panel consist of experts in homeopathy rather than merely conventional medicine. This would ensure that conventional methodologies are not used to measure the safety and effectiveness of homeopathic drugs. As a result, those drugs that are safe and effective under the standards of homeopathy would have approved monographs.

2. Disadvantages of an Intermediate Solution

Clearly, the fact that this approach would allow the marketing of drugs that are not proven effective according to conventional standards is its largest disadvantage. Requiring that homeopathic drugs have provings is not comparable to the rigorous testing required of conventional drugs. However, because of the unique nature of homeopathic drugs, it would be unreasonable to subject them to the testing standards of conventional medicine. As discussed above, the very nature of homeopathic drugs is contrary to proving their effectiveness using the conventional testing methods. By requiring that homeopathic drugs show efficacy through the mechanism of traditional provings, the FDA will ensure that homeopathic drugs are authentic as determined within the field of homeopathy rather than requiring them to show their efficacy by the incompatible processes of orthodox science. As a result, those consumers who choose to practice homeopathy will be guaranteed that they are buying safe and effective drugs as determined by homeopathic physicians.

3. Advantages of an Intermediate Solution

Allowing homeopathic drugs to submit to an intermediate review rather than to the stringent standards of conventional medicine would capture many of the advantages while not accruing the large disadvantages of subjecting them to the standards of conventional medicine.

(a) Safety

This review system would ensure that those homeopathic drugs that are on the market are in fact safe. This is important especially for those homeopathic drugs that contain known toxins. Currently, drugs that contain known toxins at low dilutions are available on a prescription-only basis. For example, although arsenic at a dilution of 6X is available OTC, 1X arsenic is only available with a prescription.¹⁹⁰ However, there is no requirement from the FDA, currently, that the 1X dilution be shown to be safe. Furthermore, the public has access (without a prescription) to homeopathic drugs that are at extremely high dilutions (such as 200X). Although “[t]hese high potency medicine are not dangerous in the traditional sense of toxicology... [t]hey are... deeper-acting medicines which have the potential to create a healing crisis—that is, an increase in certain superficial symptoms.”¹⁹¹ During these healing crises, patients experience an increase in their symptoms, which are similar to side effects associated with conventional drugs. Furthermore, homeopathic drug manufacturers probably do not report these adverse effects to the FDA.¹⁹² Because of the risk that these drugs could in fact harm consumers it is important to guarantee the safety of the patient; the proposed safety review would ensure this safety.

(b) Non-homeopathic Drugs

Furthermore, by requiring homeopathic drugs to submit to a review that is monitored by homeopathic specialties, the FDA can weed out those conventional drugs that are falsely identifying themselves as homeopathic drugs in order to avoid showing both safety and effectiveness under conventional drug standards. This would protect the consumer from conventional drugs that have not gone through the required testing and ensure that only truly homeopathic drugs bear that label. This will protect the consumer from consum-

¹⁹⁰See Ullman, *supra* note 5, at 153-54.

¹⁹¹*Id.* at 157-58.

¹⁹²National Council Against Health Fraud, *supra* note 99.

ing drugs that could very well have harmful side effects that were not detected in the pre-market approval process.

(c)

The largest advantage of this approach is that it would allow the homeopathic drug industry to continue in a safe manner without requiring that it submit to the testing standards of conventional medicine, which would most likely preclude many, if not most, homeopathic drugs from ever reaching the consumer because of the high costs associated with such rigorous testing. Unlike more strict alternatives, a requirement to show that homeopathic drugs are safe and have provings need not be preclusive for the manufacturers. In fact, many homeopathic drugs already have provided evidence of provings to the HPUS. Furthermore, many homeopathic drugs can easily be proven to be safe because of their benign active ingredients and others can be proven safe by virtue of their high dilutions. The requirement to show safety would have its largest effects on those homeopathic drugs that contain known toxins, but it is these homeopathic drugs that deserve the highest scrutiny. In addition, unlike the very time consuming and costly nature of the OTC review, which involved hundreds of thousands of drugs, a homeopathic review would only need to consider about 2,000 monographs¹⁹³ because of the limited number of active ingredients used in homeopathic drugs. As a result, a homeopathic review would be less costly for the FDA as well.

(d)

¹⁹³ See Report on the Commission Report to the European Parliament and the Council on the Application of Directives 92/73/EEC and 982/74/EEC on Homeopathic Medicinal Products, *supra* note 184, at 11.

This approach would also ensure that homeopathic drugs remain available to consumers. The FDA would not be taking efforts to quash alternative medicine by forcing it to submit to the standards of orthodox medicine, with which it is in conflict. As a result, this intermediate requirement would avoid the large political ramifications associated with undermining the homeopathic drug industry and the resulting negative effect this would have on consumer choice. This intermediate approach seeks to provide to the consumer those drugs that are in fact safe and effective according to the industry's standards. Thus, this approach would regulate homeopathic drugs so that, while it would allow consumers to use ineffective drugs according to conventional medicine standards, it would not allow them to use unsafe and unproven homeopathic drugs.

V. Choosing Among Alternatives

The difficulty in choosing among the presented alternatives is understandable because a choice among them requires a choice as between distinct paradigms. Requiring homeopathic drugs to show safety and effectiveness as with conventional drugs clearly rejects the paradigm of alternative medicine in favor of an entirely scientific and orthodox paradigm. Although this approach, which lies at one end of a spectrum of alternative reforms, has the largest costs on the homeopathic industry, it also ensures to the greatest extent the safety and effectiveness of homeopathic drugs.

At the other end of the spectrum, simply classifying homeopathic remedies as dietary supplements would allow the alternative paradigm to thrive by not subjecting these drugs to rigorous scientific testing. The obvious drawback of this solution is its inability to address at all the safety and effectiveness of these drugs.

Creating a Homeopathic Drug Review process falls at the middle of this spectrum. A review process would allow for the testing of homeopathic drugs, which would ensure consumers that these drugs are safe and effective. Yet, this testing would not undermine the alternative paradigm because it would recognize alternate forms of experimentation that could prove the safety and effectiveness of homeopathic drugs, namely provings.

The FDA, as a regulatory agency, cannot ignore the risks of public safety despite the consequences that regulating the field of homeopathic drugs will have on the industry. Thus, submitting homeopathic drugs to a review process appears to be both a viable and advantageous approach for the FDA to take with respect to the growing use and availability of homeopathic drugs. Despite the uncertainty involved with a homeopathic drug review, it is clear that some action by the FDA is appropriate. As Dr. Jonas, the scientist who conducted successful experiments of homeopathic drugs¹⁹⁴ concluded:

Alternative medicine is here to stay. It is no longer an option to ignore it or treat it as something outside the normal processes of science and medicine. The challenge is to move forward carefully, using both reason and wisdom, as we attempt to separate the pearls from the mud.¹⁹⁵

¹⁹⁴See Linde, *supra* note 43.